DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: APR 8 2004

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: **Echium Oil**

Firm: Bioriginal Food & Science Corporation

Date Received by FDA: January 23, 2004

90-Day Date: April 10, 2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang

95S-0316

RPT228

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

MAR 26 2004

Rakesh Kapoor, Ph.D.
Program Development Manager
Bioriginal Food & Science Corporation
102 Melville Street
Saskatoon, Saskatchewan
Canada S7J OR1

Dear Dr. Kapoor:

This is to inform you that the notification you submitted, dated January 12, 2004, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on January 23, 2004. Your notification concerns the substance called echium oil obtained from the seeds of *Echium plantagineum* L. that you intend to market as a new dietary ingredient.

According to the notification you state that your product will be marketed as a dietary supplement of essential fatty acids of omega 3 and omega 6 series for adults and children over the age of 12 years. You also state that echium oil will be sold as a bulk oil or as a soft gelatin capsules containing 500 to 1000 milligrams (mg) echium oil or as a blend with other nutritional oils rich in essential fatty acids such as flax seed oil, borage oil, and fish oil which will constitute between 10% to 90% of the blend. You also state as the "Inactives (composition of shell): Gelatin, glycerin, and water."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing echium oil will reasonably be expected to be safe.

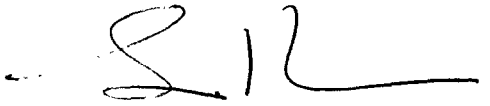
There is little or no history of use of echium oil in the food supply. The safety profile submitted in the notification is inadequate to support the safety of echium oil. No toxicological studies have been conducted using the refined oil. According to the notification, a few toxicological studies in rats were conducted using the plant, *Echium plantagineum* L., however, the notification did not address the compositional similarities and differences between the plant and the refined echium oil. It is unclear to us how the test substances used in the studies submitted relate qualitatively and quantitatively to the echium oil you plan to market.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing echium oil when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of January 23, 2004. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information that you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
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Bioriginal

Bioriginal Food & Science Corp.

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Ph 306 975 1166
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January 8, 2004

VIA COURIER

Felicia B. Satchell
Director
Division of Food Labeling and Standards
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740
Phone Number: (301) 436-2371

Attention: Felicia B. Satchell

Dear Ms. Satchell:

Re: New Dietary Ingredient Notification for Echium Oil

As required under 21CFR190.6, I am submitting one original and two copies of the New Dietary Ingredient Notification on Echium oil. Unless otherwise directed, Bioriginal Food and Science Corp. plans to market this product in the U.S.A. subsequent to the requisite 75-day waiting period enforced after receiving your acknowledgement of the receipt of this application.

If you have any question, please let me know by email, fax or phone. Contact information is provided below.

Thank you.

Sincerely,

Rakesh Kapoor, Ph.D.
Product Development Manager
Ph.: (306) 975 9265
Fax: (306) 242 3829
Email: rkapoor@bioriginal.com

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ENTREPRENEUR OF THE YEAR

Premarket notification for Echium oil for use in dietary supplements in the US *(Federal Register, 62 (184), p49886-49892)*[1]

1) *The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient.*

Manufacturer:

Bioriginal Food & Science Corp
102 Melville Street, Saskatoon
SK, S7J 0R1, Canada
Ph: (306) 975 1166
Fax: (306) 242 3829
Email: business@bioriginal.com

2) *The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical.*

Echium oil obtained from the seeds of Echium plantagineum. The taxonomic details of the plant are as below:

Taxonomy (Linnaeus):
Division: Spermatophyta
Subdivision: Angiospermae
Class: Dicotyledonae
Family: Boraginaceae
Genus: Echium
Species: plantagineum

Boraginaceae is a large plant family with approximately 100 genera and 2500 species that are widely distributed throughout the Northern Hemisphere [1]. The family is well known to herbalists and gardeners because it includes many ornamental plants [1].

The genus Echium contains about 30 species distributed across Europe, the Mediterranean region, Madeira, the Canaries and the Azores [2].

Echium plantagineum is an erect biennial 20-60 cm high, softly hairy, with one or many flowering stems [2]. The basal leaves are ovate with prominent lateral veins and soft appressed setae [2]. The cauline leaves are oblong to lanceolate, the uppermost being more or less cordate at the base [Ref 2]. Inflorescence usually branched [2]. Calyx 7-10mm at anthesis, up to 15mm in fruit [2]. Corolla 18-30mm infundibuliform blue becoming pink through purple, hairy on veins and margins only [2]. Two stamens exerted from corolla tube, the remaining stamens included or only slightly [2]. Stigmae distinctly bifid [2].

Echium plantagineum is also known by the common names of Purple Vipers Bugloss, Paterson's Curse and Salvation Jane.

3) *A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:*

   (i) The level of the new dietary ingredient in the dietary supplement;

[1] After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

Echium oil will be sold as a bulk oil to encapsulators/Dietary supplement manufacturers, or as soft gelatin capsules containing 500 to 1000 mg Echium oil or as a blend with other nutritional oils rich in essential fatty acids from the list below, to dietary supplement manufacturers and distributors.

Flax seed oil
Borage oil
Fish oil

These oils will constitute between 10 to 90% of the blend. An example of the blend is:

Ingredient	% Composition	Quantity
Echium oil	50% w/w	600 mg
Fish oil	25% w/w	300 mg
Borage oil	25% w/w	300 mg
Fill weight of capsule		1200 mg
Total weight of capsule including shell		1600 mg

Inactives (composition of shell): Gelatin, glycerin, water.

(ii) The conditions of use recommended or suggested in the labeling. If no conditions of use are recommended or suggested in the labeling of the dietary supplement then the ordinary conditions of use of the supplement.

Echium oil will be marketed as a dietary supplement of essential fatty acids of omega 3 and omega 6 series for adults and children over the age of 12 years. As it is enriched in gamma-linolenic acid (omega-6 fatty acid) and stearidonic acid (omega-3 fatty acid), it will bypass the need for delta-6-desaturase, a rate limiting enzyme in the metabolism of linoleic acid (omega-6 essential fatty acid) and alpha-linolenic acid (omega-3 essential fatty acid).

4) The history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language it shall be accompanied by an accurate and complete English translation.